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Can shared medical appointments in general practice support people living with chronic obstructive pulmonary disease in the North East and North Cumbria region of England?

Submission date
13/02/2023

Recruitment status
No longer recruiting

Registration date
03/03/2023

Overall study status
Ongoing

Last Edited
06/08/2024

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a lung condition that affects over a million people in England. It is most common in people living in deprived areas. The main symptom is breathlessness, which can suddenly worsen resulting in hospital care. There is no cure for COPD, so we need to support patients to manage their condition themselves, by monitoring symptoms, using inhalers and other medication correctly and by seeking help only when needed.
Self-management support is given during check-up appointments in general practice, yet patients report there is not enough time for discussion. Some practices are trying shared medical appointments (SMAs), where a group of 6-12 patients, with the same condition, share a longer appointment. Patients can ask staff questions and share their experiences with the group. It is not known how well shared medical appointments work for patients with COPD or whether it is more costly than usual care. Recently, more care is being delivered by video, but it is not known if this is possible in groups of patients. This study will test these ideas in a small study to help decide if a larger, more expensive, trial is possible in the future.

Who can participate?
Patients aged 18 years or older with a diagnosis of COPD under ongoing management in a GP practice in the North East and North Cumbrian region of England

What does the study involve?
Participants will be randomly allocated to attend a shared appointment in person or by video link, or receive usual care. The researchers will:
1. Measure the number of patients that take part and remain in the study
2. Interview patients about experiences in the study
3. Test how to collect information from patients about NHS use
4. Interview staff about how well shared appointments work
5. Test how to collect information about the time and money needed to run SMAs
6. Use their findings to decide if a larger trial is possible

What are the possible benefits and risks of participating?
Participants will help the researchers to better understand how well these shared appointments work and who they work for. Participants who attend an SMA as part of the study will receive support from healthcare professionals and other people living with COPD. Participants who attend usual care as part of this study will be helping to provide the researchers with important information that allows them to compare SMAs with usual one-to-one appointments. If SMAs are found to be as good as or better than usual appointments, they might become a part of routine COPD care in future.
With regards to risks, participants may find completing study questionnaires, attending an SMA and/or an interview time-consuming. If they attend an SMA they may feel uncomfortable discussing their health condition in front of people with COPD. Participants can choose not to share information about themselves during the session if they wish. Everyone who participates in the study is required to agree not to discuss the health issues of others with people outside the group.

Where is the study run from?
The study is being run by North of England Commissioning Support (NECS) and The University of Newcastle Upon Tyne (UK)

When is the studying starting and how long is it expected to run for?
September 2022 to March 2026

Who is funding the study?
NIHR Research for Patient Benefit (UK)

Who is the main contact?
Dr Karen Marshall, Karen.marshall1@newcastle.ac.uk

Study website
https://research.ncl.ac.uk/smartcopdtrial/

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
315909

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 315909, CPMS 54981

Study information

Scientific Title
Shared medical appointments in primary care for improving self-management of chronic obstructive pulmonary disease amongst underserved groups: a feasibility randomized control trial in North East and North Cumbria

Acronym
Feasibility RCT: SMAs for COPD in primary care

Study objectives
This study aims to establish the feasibility and acceptability of conducting a randomized control trial (RCT) that compares the use of shared medical appointments (SMA) delivered in-person

(PSMAs) or by video-link (VSMA) with usual care with regards to improving self-management of chronic obstructive pulmonary disease (COPD) amongst patients living in under-served communities in North East and North Cumbria (NENC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/03/2023, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 1224 558458; gram.nosres@nhs.scot), ref: 23/NS/0022

Study design
Feasibility randomized controlled trial with mixed-methods evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Participants will be randomly allocated to attend a shared appointment in-person or by video link, or receive usual care. The researchers will:
1. Measure the number of patients that take part and remain in the study
2. Interview patients about experiences in the study
3. Test how to collect information from patients about NHS use
4. Interview staff about how well shared appointments work
5. Test how to collect information about the time and money needed to run SMAs
6. Use their findings to decide if a larger trial is possible

A number generator will be used to randomize the patients in a ratio of 1:1:1 to either the in-person SMA arm, video SMA arm or usual care arm of the trial using variable length random permuted blocks within strata.

Participants randomized to the treatment arms will attend a single, 90-minute shared medical appointment delivered by a team of staff from participating primary care practices.

Participants allocated to receive usual care (control arm) will receive no additional intervention. Usual care typically includes an annual review delivered 1:1 in person, pulmonary rehabilitation

(if appropriate) and primary and secondary care treatment for exacerbations. Primary care visits tend to be 1:1 appointments with the nurse practitioner/ pharmacist that last 10-15 minutes. It is also possible that they may be referred, or self-refer, to attend a 1:1 appointment with a social prescribing link-worker.

Follow-up will occur approximately 6 months from baseline (3 months post intervention) and again at 12 months from baseline (9 months post intervention.) This will involve the completion of study questionnaires either hard copies returned by free post, over the telephone with the research team or via online form.

A sample of participants will be invited to participate in a 1:1 qualitative interview with the research team to explore their views and experiences of the SMA and study processes. This will take place within approximately 8 weeks of the intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rates measured using screening logs at end of the recruitment period
2. Retention and attrition rates i.e. the proportion of participants that attend the PSMA/VSMA and the proportion of participants that return and complete questionnaires at 6 and 12 months
3. Completion rates of study questionnaires and proformas (including those to collect economic data):
3.1. Knowledge, skills and confidence to manage their own health and wellbeing measured by Patient Activation Measure at baseline, 3 months post-intervention and 9 months post-intervention
3.2. Anxiety and depression symptoms measured using Health, Anxiety and Depressions Scale at baseline, 3 months post-intervention and 9 months post-intervention
3.3. Quality of life measured using EQ-5D-5L at baseline, 3 months post-intervention and 9 months post-intervention
3.4. Healthcare service use measured by Patient care use questionnaire at baseline, 3 months post-intervention and 9 months post-intervention
3.5. Healthcare service use measured by screening logs and case report form at 12 months
3.6. Time and travel costs measured using Patient Time and Travel questionnaire at 1 month post-intervention
3.7. Primary care costs (staff time and consumables) measured using resource use proforma within 2 weeks of the intervention

Secondary outcome measures
Acceptability and feasibility of SMAs and study processes: willingness to enter the trial, the acceptability of the study design, attendance at the SMAs and acceptability of the PAM questionnaire as the proposed outcome measure, collected by qualitative interviews with patient participants and interventionists within 8 weeks of the intervention

Overall study start date
12/09/2022

Completion date
11/03/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older with a diagnosis of COPD
2. Under ongoing management in general practice
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
132

Key exclusion criteria
1. Without the capacity to consent i.e., with dementia or significant learning difficulties
2. With severe mental ill-health
3. Requiring palliative care
4. Diagnosed with a condition likely to limit life expectancy to <1 year

Date of first enrolment
07/02/2024

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: North East and North Cumbria
Regent Point
Regent Farm Road
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Newcastle upon Tyne Tyne and Wear
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Sponsor information

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Sponsor type
University/education

Website
http://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
11/12/2027

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be fully anonymised, and, with permission of participants, stored in a publicly available repository (e.g. data.ncl or open science framework) for at least 10 years.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	15/03/2023	02/06/2023	No	Yes
Protocol file	version 2	27/03/2023	02/06/2023	No	No
HRA research summary			26/07/2023	No	No